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10/507,252

01/28/2005

Jef D Boeke

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EXAMINER

MARTIN, PAUL C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

12/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/507,252 | Applicant(s) BOEKE ET AL. | |
| | Examiner PAUL C. MARTIN | Art Unit 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 22-75 and 77-81 is/are pending in the application.
- 4a) Of the above claim(s) 22-75 and 79-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 77 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14, 22-75 and 77-81 are pending in this application, Claims 22-75 are acknowledged as withdrawn, Claims 1-14 and 77-81 were examined on their merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/06/08 has been entered.

Election/Restrictions

Newly submitted claims 79-81 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claimed invention, Group I (Claims 1-14, 77 and 78) is drawn to a method of identifying an agent that inhibits reverse transcriptase comprising the steps of contacting a cell comprising a divalent cation transporting protein with a test agent, detecting a change in the concentration of intracellular manganese and detecting reverse transcriptase activity in the cell using a polyribonucleotide or polydeoxyribonucleotide template.

Group II (Claims 79-81) is drawn to a method of identifying an agent that inhibits reverse transcriptase comprising the steps of contacting a cell comprising a divalent cation transporting protein with a test agent, detecting a change in the concentration of intracellular manganese and detecting inhibition of retrotransposable element replication, wherein the retrotransposable element is either HIV or a Ty1 retrotransposon.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because as discussed in the Original Restriction mailed on 03/12/07 under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Wei *et al.* (J. Biol. Chem., 2000) teach a method of modulating manganese transport in cells. They teach that by mutating certain residues in the membrane-bound manganese transporter protein Pmr1, one can alter the manganese transport of yeast, cells. The mutations of Pmr1 are introduced by transformation of the yeast with a plasmid vector coding for mutated Pmr1; these plasmids are translated and the mutant Pmr1 alleles are inserted in the yeast membrane, reading on identifying agents that modulate manganese transport by contacting a cell membrane with unknown agents (see Experimental Procedures, p. 23928, col. 1; see Fig. 1B, p. 23929; see Results, p. 23928 col. 1 last paragraph to col. 2, first paragraph, as examples). Because manganese modulates reverse transcriptase activity, it is inherent that agents that modulate manganese concentration in cells also modulate reverse transcriptase activity.

Because the step of modulating manganese transport in a cell by contacting the cell with an agent is common to all Groups listed above, except Group V, the Groups were deemed to lack unity of invention and were properly restricted. Newly added Claims 79-81 would have been separately restricted if presented originally.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 79-81 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-14, 77 and 78 were examined on their merits.

The rejection of Claims 6-9 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, has been withdrawn due to the Applicant's amendments to the claims filed 09/03/08.

The rejection of Claims 1, 6, 7, 10-14 and 76-78 under 35 U.S.C. § 102(b) as being anticipated by Okorokov *et al.* (1977) as evidenced by Bates *et al.* (2005) has been withdrawn due to the Applicant's amendments to the claims filed 09/03/08.

Art Unit: 1657

The rejection of Claims 1-4, 6, 7, 10-14 and 76-78 under 35 U.S.C. § 103(a) as being unpatentable over Okorokov *et al.* (1977) as evidenced by Bates *et al.* (2005) has been withdrawn due to the Applicant's amendments to the claims filed 09/03/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 19, 20 and 76-78 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 is directed to the measurement of reverse transcriptase activity and consists of three method steps 1) contacting a cell comprising a divalent cation transporting protein with a test agent, 2) detecting a change in the concentration of intracellular manganese in the cell after contact with the test agent as compared to the concentration of manganese ion levels in the absence of test agent, and 3) detecting reverse transcriptase activity using polynucleotide templates.

Art Unit: 1657

Claim 1, as written, is merely a method of identifying an agent which elevates intracellular manganese ion concentration in a cell and detecting an agent which inhibits reverse transcriptase in a cell. Any speculation as the effect thereof of intracellular manganese on reverse transcriptase activity is solely a mental step or calculation on the part of the Applicant. In effect, there is a disconnect between a method for measuring intracellular manganese ion concentrations and reverse transcriptase activity such that one of ordinary skill in the art would be unable to use the invention as claimed. The claimed invention, as written, consists of two separate assay steps with no correlation established between the two measurements. One of ordinary skill in the art would in effect be taught how to assay for an agent that elevates intracellular manganese ion concentrations in a cell and how to assay for an agent which inhibits reverse transcriptase activity in a cell, but would not have been reasonably taught a method to identify an agent that inhibits reverse transcriptase activity in a cell based upon an observable decrease in activity of reverse transcriptase coupled with an observed increase in intracellular manganese. If the intracellular manganese concentration is observed to decrease one would not expect to observe a concurrent decrease in the activity of reverse transcriptase in the claimed method and therefore the invention was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

12/4/08

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657